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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/19/2005

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

01/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,973	<b>Applicant(s)</b> GAZZA, GIANLUCA	
	<b>Examiner</b> DIANNE DORNBUSCH	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 72-101, 105, 113 and 114 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72-101, 105, 113 and 114 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 9, 2009 has been entered.

### *Specification*

2. The disclosure is objected to because of the following informalities: on page 3 lines 15-19 claims 1 and 34 are referred to but they no longer exist.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

**Comment [11]:** there are no 101 issue ... the claims are not identical

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 72-101, 105, 113, and 114 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation in claims 72, 101, and 105 regarding the limitation that the wall cavity

following the balloon structure outline from the proximal end to the distal end. This is considered new matter since the original disclosure does not show it following the outline near the proximal end, such as seen in Fig. 1 where the slope in the proximal portion is different.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 79 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 79 recites "a proximal shank" which is unclear to the examiner if applicant is referring to another shank or the same proximal shank claimed in claim 72. For purposes of this action it is considered as the same one.

Claim 79 recites the limitation "the proximal tubular portion" in the 2<sup>nd</sup> line. There is insufficient antecedent basis for this limitation in the claim.

The proximal tubular portion is introduced in claim 78 not 72.

7. Claims 81 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 81 recites "a distal connecting shank" which is unclear to the examiner if applicant is referring to another shank or the same distal shank claimed in claim 72. For purposes of this action it is considered as the same one.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 72-79, 81, 83-86, 100, 101, 105, 113, and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Shonk (5,304,135).

Shonk discloses the following claimed limitations:

Claims 72, 101, and 105: An inflatable balloon structure (12) for catheters, the balloon structure being of predominant longitudinal extent with a proximal end (16) and a distal end (14), and being suitable for performing an expansion in an object to be dilated (Fig. 1), the balloon structure comprising a proximal shank (see figure below), a distal shank (see figure below) and an intermediate portion (18) between said proximal and distal shanks (see figure below), said balloon structure including the proximal and distal shanks, having a wall (see figure below) which, when the inflation chamber is expanded, has an outer surface (see figure below) of circular cross-section transverse to the longitudinal extent of the balloon structure (see figure below), and an inner surface (see figure below) which delimits an inflation chamber (20), in which at least one wall cavity (30) is provided in the wall (Fig. 3) between the outer surface and the inner surface (see figure below), the wall cavity extending without interruptions and/or openings, longitudinally relative to the balloon structure, between the proximal end and the distal end,

the wall cavity following the balloon structure outline from the proximal end to the distal end (Fig. 1).

Claim 73: That when the balloon structure is inflated or expanded, the outer surface of the intermediate portion is free of protuberances or recesses (Fig. 1 and 3).

Claim 74: That the wall cavity is within the wall which delimits the inflation chamber for the whole of its extent which affects the balloon structure (see figure below).

Claim 75: That the balloon structure is inflated or expanded, the outer surface of the intermediate portion is cylindrical (Fig. 3).

Claim 76: When the inflation chamber is expanded, the balloon structure has an annular cross-section of the outer surface, transverse the longitudinal extent of the balloon structure (Fig. 3).

Claim 77: When the inflation chamber is expanded, the balloon structure has a substantially circular cross-section of the outer surface, transverse the longitudinal extent of the balloon structure (Fig. 3).

Claim 78: That the balloon comprises a proximal tubular portion (see figure below) in the vicinity of the proximal end (see figure below).

Claim 79: That the balloon comprises a proximal shank (see figure below) connecting the proximal tubular portion and an intermediate portion (see figure below).

Claim 81: That the balloon comprises a distal connecting shank (see figure below) between the intermediate portion and a portion for connection to a distal catheter tip (see figure below).

Claim 83: That the wall cavity is separated from the inflation chamber by an internal portion of the wall (52, 56).

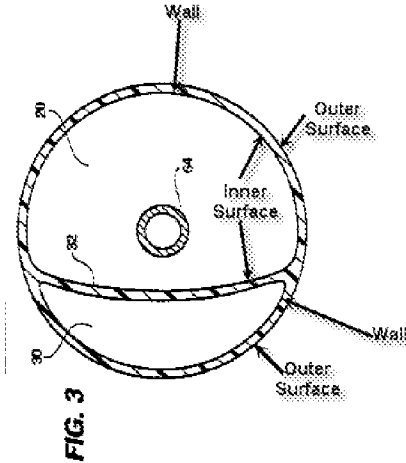
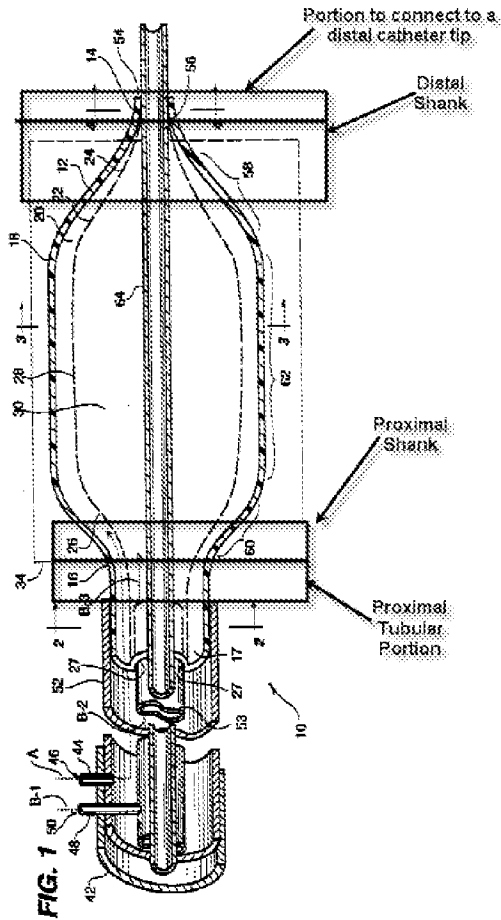
Claim 84: That the cavity is separated from the outer surface by an external portion of the wall (see figure below).

Claim 85: When the balloon structure is inflated or expanded, the inner surface of the intermediate portion is smoothed, rounded, or free of sharp corners (Fig. 1 and 3).

Claim 86: When the balloon structure is inflated or expanded, the inner surface of the intermediate portion has an annular cross-section, transverse the longitudinal extent of the balloon (Fig. 1 and 6).

Claims 100 and 113: That the inflation chamber is closed in a leak tight manner (there cannot be any leaks since it would cause the balloon to not completely inflate) onto an apex tip (Fig. 1), leaving solely openings for access to one or more guide-wire cavities (Fig. 3).

Claim 114: That the balloon structure is connected proximally to a shaft (Fig. 1) comprising an inflation cavity connected to the inflation chamber in a leak tight manner for the flow of a fluid from the shaft to the inflation chamber and vice versa (Fig. 1) (there cannot be any leaks since it would cause the balloon to not completely inflate).



10. Claims 87, 88, 91-95, and 97 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shonk (5,304,135).

Claim 87:

Shonk discloses each and every structural element of the balloon structure see Fig 1 and 3.



Shonk teaches that the balloon structure is made of a polymer (Col. 5 Lines 5-20), but is silent as to the method of making the structure. The claimed phrase “produced from an extruded tube having at least two cavities” is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Shonk is silent as to the process of making the structure, it appears that the product in Shonk would be the same or similar as that claimed.

Claim 88:

Shonk discloses each and every structural element of the balloon structure see Fig 1 and 3. Shonk teaches that the balloon structure is made of a polymer (Col. 5 Lines 5-20), but is silent as to the method of making the structure. The claimed phrase “that prior to the deformation of a cavity of the extruded tube to form an inflation chamber, the extruded tube has an at least partially flat partition separating the at least two cavities ” is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Shonk

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is silent as to the process of making the structure, it appears that the product in Shonk would be the same or similar as that claimed.

Claims 91-95 and 97:

Shonk teaches that the balloon structure comprises a polymer (Col. 5 Lines 5-20) with at least two cavities (Fig. 3); the balloon structure having two to three materials (Col. 5 Lines 5-20); that the material that delimits the inflation cavity is a material that is semi-compliant (since the this material is the outer wall of the balloon it is compliant in order to allow the balloon to inflate to a maximum point); that the second material forms the wall portion which separates the wall cavity from the outer surface (Fig. 3) and has a greater flexibility than the first material (if the first material is the material that delimits the inflation cavity, then when the balloon is inflated it reaches a maximum where it is not as flexible as the second material).

Shonk teaches all the limitations discussed above but is silent as to the method of making the balloon structure. The claimed phrases describing the method of making the balloon structure such as the method of producing the balloon structure through a co-extruded tube are being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 80, 82, 89, 90, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shonk (5,304,135).

Claims 80 and 82:

Shonk discloses the claimed invention except for the internal taper angle of the proximal and distal shank ranges from 20-40 degrees, preferably 30 degree. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a tapered angle between 20 to 40 degree, preferably 30 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 89 and 90:

Shonk discloses each and every structural element of the balloon structure see Fig 1 and 3. Shonk teaches that the balloon structure is made of a polymer (Col. 5 Lines 5-20), but is silent as to the method of making the structure. The claimed phrase "prior to the deformation of a cavity of the extruded tube to form an inflation chamber, the extruded tube has a partition separating the at least two cavities which partition has, in cross-section transverse the extruded tube" is being treated as a product by process

limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Shonk is silent as to the process of making the structure, it appears that the product in Shonk would be the same or similar as that claimed.

Furthermore, Shonk discloses the claimed invention except for the minimum thickness of the partition separating the two cavities prior to deformation of the cavities being between 55% and 100% (claim 89) or between 60% and 70% (claim 90) of the minimum thickness of the wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the partition to be a minimum thickness between 55% and 100% or 60% and 70% of the minimum thickness of the wall, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 98 and 99:

Shonk discloses the claimed invention except for the thickness of the wall portion separating the wall cavity and the inflation chamber when the balloon structure is inflated/expanded is between 55% and 100% (claim 98) or between 60% and 70% (claim 99) of the thickness of the wall portion that separates the wall cavity from the outer surface. It would have been obvious to one having ordinary skill in the art at the

time the invention was made to have the wall portion separating the wall cavity and the inflation chamber to have a thickness between 55% and 100% or 60% and 70% of the of the wall portion that separates the wall cavity from the outer surface, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shonk (5,304,135) in view of Werneth et al. (6,576,001).

Shonk teaches all the claimed limitations discussed above however, Shonk does not disclose that the wall cavity is coated with or delimited by a layer of material with a coefficient of friction such as to facilitate the sliding of a guide wire housed in the wall cavity.

Werneth discloses that the wall cavity (424) is coated with or delimited by a layer of material (lubricous coating) with a coefficient of friction such as to facilitate the sliding of a guide wire housed in the wall cavity (Col. 25 Lines 38-41).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Shonk with a lubricous coating in view of the teachings of Werneth, in order to facilitate the sliding of the catheter over the guidewire (Col. 25 Lines 38-41).

#### ***Response to Arguments***

14. Applicant's arguments filed October 9, 2009 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773